UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL
SAFETY AND POLLUTION
PREVENTION

MEMORANDUM

Date: December 25, 2018

Subject: Efficacy Review for Everclean,
EPA File. No. 777-RGL,
DP Barcode: #448737
E-submission: #31254

From: Sophie Nguyen
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P)

Thru: Kristen Willis, Team Leader
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P)
Date Signed: 12/19/2018

To: Jacqueline Hardy RM34/Stacey Grigsby
Regulatory Management Branch II
Antimicrobials Division (7510P)

Applicant: Reckitt Benckiser Inc.
Morris Corporate Center IV
399 Interpace Parkway
Parsippany, NJ 07054-0225

Formulation from the Label:

Active Ingredient	% by wt.
Citric acid	2.50 %
Other Ingredients	97.50%
Total	100.00%

I. BACKGROUND

Product Description (as packaged and applied): To be applied as a ready to use liquid

Submission Type: New product registration.

Requested Action: Registrant is requesting to register a new product, Everclean. The product is a disinfectant for use on hard, non-porous surfaces

Documents Submitted for Consideration:

- A letter to EPA (dated August 2, 2018)
- Application for Pesticide Registration (EPA form 8570-1)
- Confidential Statement of Formula (EPA form 8570-4)
- Certification with Respect to Citation of Data (EPA form 8570-34)
- Data Matrix (EPA Form 8570-35)
- 7 efficacy studies (MRID Nos. 50598914 - 50598920); Statement of No Data Confidentiality Claims, Good Laboratory Practice Statement, and Quality Assurance Unit Summary were included with the study.
- Proposed product label dated August 2, 2018.

II. USE DIRECTIONS

To Disinfect/Sanitize (hard non-porous surfaces): Apply until thoroughly wet. Leave for 30 seconds to sanitize. Leave for 10 minutes to disinfect. Wipe dry. Rinse food contact surfaces (and toys) with water.

III. AGENCY STANDARDS FOR PROPOSED CLAIMS

Disinfectants for Use on Hard, Non-porous Surfaces in Hospital or Medical Environments:
The effectiveness of disinfectants for use on hard surfaces in hospital or medical environments must be substantiated by data derived using the AOAC Use-Dilution Method (UDM) (for water soluble powders and liquid products) or the AOAC Germicidal Spray Products Test (GST) (for spray products). Sixty carriers must be tested against each of the three batches of the product at the active ingredient(s) lower certified limit(s) (LCL). For UDM, a mean log density of at least 6.0 (corresponding to a geometric mean density of 1.0×10^6) and not above 7.0 (corresponding to a geometric mean density of 1.0×10^7) for *Staphylococcus aureus* (ATCC 6538) and *Pseudomonas aeruginosa* (ATCC 15442). A mean log density <6.0 or >7.0 invalidates the test. For GST, a mean log density of at least 5.0 (corresponding to a geometric mean density of 1.0×10^5) and not above 6.5 (corresponding to a geometric mean density of 3.2×10^6) for *Staphylococcus aureus* (ATCC 6538) and *Pseudomonas aeruginosa* (ATCC 15442). A mean log density <5.0 or >6.5 invalidates the test. To support products labeled as "disinfectants", killing on 59 out of 60 carriers for germicidal spray testing (GST) is required. For AOAC Use-Dilution testing (UDM), conduct three independent tests (i.e., three batches at the LCL tested on three different test days) against the test microbe. The performance standard for *S. aureus* is 0-3 positive carriers out of sixty. The performance standard for *P. aeruginosa* is 0-6 positive carriers out of sixty. Thus, a total of three tests for *S. aureus* and three tests for *P. aeruginosa* are necessary. Sixty carriers are required per test, without contamination in the subculture media. Contamination of only one carrier (culture tube) is allowed per 60-carrier set; occurrence of more than one contaminated carrier invalidates

the test results for both UDM and GST methods. To be deemed an effective product, the product must pass all tests for both microbes. All products should meet the performance standard associated with the method and microbe at ≤ 10 minutes of contact.

Virucides:
The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray disinfectants) must be used. To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of 2 different product lots of disinfectant at LCL must be tested against a recoverable virus titer of at least 10^4 from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique, using a minimum of four determinations per each dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level.

Sanitizer Test (for inanimate, non-food contact surfaces):
The effectiveness of sanitizers for non-food contact surfaces must be supported by data that show that the product will substantially reduce the numbers of test bacteria on a treated surface over those on an untreated control surface. The Agency recommends the American Society for Testing and Materials (ASTM) Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (E1153) (Ref. 1). The test surface(s) should represent the type(s) of surfaces recommended for treatment on the label, i.e., porous or non-porous. Products that are represented as "one-step sanitizers" should be tested with an appropriate organic soil load, such as 5 percent serum. For hard, porous surface label claims use unglazed ceramic tile. For hard, nonporous surface label claims use stainless steel carrier or glass slide. Use 5 test carriers and 3 control carriers. Tests should be performed with each of 3 product samples, representing 3 different product lots, tested at LCL against *Staphylococcus aureus* (ATCC 6538) and either *Klebsiella pneumoniae* (aberrant, ATCC 4352) or *Enterobacter aerogenes* (ATCC 13048 or 15038). The ASTM method states that the inoculum employed should provide a count of at least 7.5×10^5 colony forming units per carrier. The performance measure should demonstrate a reduction of ≥99.9% (a 3-$\log_{10}$ reduction) in the number of each test microorganism over the parallel control count within 5 minutes.

Supplemental Claims:
An antimicrobial agent identified as a "one-step" disinfectant or as effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as 5 percent serum. On a product label, the hard water tolerance level may differ with the level of antimicrobial activity (e.g., sanitizer vs. disinfectant) claimed. To establish efficacy in hard water, all microorganisms (i.e., bacteria, fungi, and viruses) claimed to be controlled must be tested by the appropriate Recommended Method at the same tolerance level.

Agency Standards for Making Viral Emerging Pathogen Claims in accordance with the agency publication *Guidance to Registrants: Process for Making Claims against Emerging Viral Pathogens not on EPA-registered Disinfectant Labels*.:

1. The product is an EPA-registered, hospital/healthcare or broad-spectrum disinfectant with directions for use on hard, non-porous surfaces.

2. The currently accepted product label should have disinfectant efficacy claims against at least one of the following viral pathogen groupings**:**

For an emerging viral pathogen that is a/an…	*Qualifying criterion*
Enveloped virus emerging viral pathogen	At least one large OR one small non-enveloped virus
Large, non-enveloped emerging viral pathogen	At least one small, non-enveloped virus
Small, non-enveloped emerging viral pathogen	At least two small, non-enveloped viruses with each from a different viral family

IV. SYNOPSIS OF SUBMITTED EFFICACY STUDY

1.	**MRID**	50598914			
Exp. Start Date		3/5/18	**Study Completion Date:**		6/29/18
Study Objective		Hard, non-porous surface disinfectant			
Study Title		AOAC Germicidal Spray Method			
Testing Lab, Lab Study ID		Accuratus Lab Services, Project #A25082			
Test organism(s) ☒ **1** ☐ **2** ☐ **3** ☐ **4+**		*Pseudomonas aeruginosa* (ATCC 15442)			
Test Method		AOAC Official Method 961.02, Germicidal Spray Products as Disinfectants (2012), Protocol #REK01121417.GS.1			
Application Method		Ready-to-use, trigger spray			
Test Substance Preparation	**Name/ID**	Everclean; e0111-136A			
	Lots ☐ **1** ☐ **2** ☒ **3**	Final Test Substance Certificates of Analysis: 2182-165: 2.34% Citric acid 2182-145: 2.38% Citric acid 2182-146: 2.37% Citric acid Tested concentration: LCL			
	Preparation	Ready-to-use spray at a distance of 6-8 inches using 3 sprays			
Soil load		5% FBS			
Carrier type, # per lot		Glass slides, 60 per batch			
Test conditions		**Contact time**	5 min.	**Temp**	20-21°C
Neutralizer		20 mL Letheen Broth + 0.07% Lecithin + 0.5% Tween 80		**Incubation**	46-48 hrs. at 36°C
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		**Test History**: On test date 3/5/18, Batch 2182-144 was inadvertently used in testing, instead of Batch 2182-165 as has been directed by the Sponsor (see Protocol Amendment). Additionally, Batches 2182-145 and 2182-146 were tested on 3/5/18. Data for these batches is valid and is presented in the body of the report. Batch 2182-165 was tested on 3/12/18. All data from Batch 2182-144 is invalid and presented in Attachment I. Data from			

	Batch 2182-165 is valid and is presented in the body of the report. **Protocol Amendments:** Per Sponsor request, the protocol was amended to update the test substance lot numbers. Batch 2182-165 is to replace Batch 2182-144. All testing data from Batch 2182-144 is considered invalid.

2.	**MRID**	50598915			
Exp. Start Date		3/5/18	**Study Completion Date:**		6/29/18
Study Objective		Hard, non-porous surface disinfectant			
Study Title		AOAC Germicidal Spray Method			
Testing Lab, Lab Study ID		Accuratus Lab Services, Project #A25083			
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		*Staphylococcus aureus* (ATCC 6538)			
Test Method		AOAC Official Method 961.02, Germicidal Spray Products as Disinfectants (2012), Protocol #REK01121417.GS.2			
Application Method		Ready-to-use, trigger spray			
Test Substance Preparation	**Name/ID**	Everclean; e0111-136A			
	Lots **☐ 1 ☐ 2 ☒ 3**	Final Test Substance Certificates of Analysis: 2182-165: 2.34% Citric acid 2182-145: 2.38% Citric acid 2182-146: 2.37% Citric acid Tested concentration: LCL			
	Preparation	Ready-to-use spray at a distance of 6-8 inches using 3 sprays			
Soil load		5% FBS			
Carrier type, # per lot		Glass slides, 60 per batch			
Test conditions		**Contact time**	5 & 10 min.*	**Temp**	19-20°C
Neutralizer		20 mL Letheen Broth + 0.07% Lecithin + 0.5% Tween 80		**Incubation**	46-47 hrs. at 36°C
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		*Batch 2182-146: 5 min.; Batches 2182-145 and 2182-165: 10 min. **Test History**: Testing performed on 3/5/18 resulted in failing efficacy results for Batch 2182-145 and Batch 2182-165. Per Sponsor's request, the protocol was amended to add additional testing of both batches using an exposure time of 10 minutes (See Protocol Amendment 2). Batch 2192-145 and Batch 2182-165 were tested on 3/21/18, using an exposure time of 10 minutes, which resulted in valid test results. Testing performed on 3/5/18 and 3/21/18 are both valid and presented in the body of the report. **Protocol Amendments:**			

	Per Sponsor request, the protocol was amended to update the test substance lot numbers. Batch 2182-165 is to replace Batch 2182-144. Per Sponsor's request, the test substance exposure time is to be updated to 10 minutes for testing against Batches 2182-165 and 2182-145.

3.	**MRID**	50598916			
Exp. Start Date		3/5/18	**Study Completion Date:**		6/29/18
Study Objective		Hard, non-porous surface disinfectant			
Study Title		AOAC Germicidal Spray Method			
Testing Lab, Lab Study ID		Accuratus Lab Services, Project #A25084			
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		*Salmonella enterica* (ATCC 10708)			
Test Method		AOAC Official Method 961.02, Germicidal Spray Products as Disinfectants (2012), Protocol #REK01121417.GS.3			
Application Method		Ready-to-use, trigger spray			
Test Substance Preparation	**Name/ID**	Everclean; e0111-136A			
	Lots **☐ 1 ☐ 2 ☒ 3**	Final Test Substance Certificates of Analysis: 2182-165: 2.34% Citric acid 2182-145: 2.38% Citric acid 2182-146: 2.37% Citric acid Tested concentration: LCL			
	Preparation	Ready-to-use spray at a distance of 6-8 inches using 3 sprays			
Soil load		5% FBS			
Carrier type, # per lot		Glass slides, 60 per batch			
Test conditions		**Contact time**	5 min.	**Temp**	19°C
Neutralizer		20 mL Letheen Broth + 0.07% Lecithin + 0.5% Tween 80		**Incubation**	47 hrs. at 36°C
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		**Protocol Amendments:** Per Sponsor request, the protocol was amended to update the test substance lot numbers. Batch 2182-165 is to replace Batch 2182-144.			

4.	**MRID**	50598917		
Exp. Start Date		3/12/18	**Study Completion Date:**	6/27/18
Study Objective		Non-Food Contact Sanitizer		
Study Title		Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Modification for Spray Product Application)		
Testing Lab, Lab Study ID		Accuratus Lab Services, #A25109		
Test organism(s) **☐ 1 ☒ 2 ☐ 3 ☐ 4+**		*Enterobacter aerogenes* (ATCC 13048) *Staphylococcus aureus* (ATCC 6538)		
Test Method		Accuratus Lab Services Protocol #REK01121417.NFS		

		Modified ASTM Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces, E1153-14, AOAC Official Method 960.09 Germicidal and Detergent Sanitizing Action of Disinfectants, 2013, AOAC Official Method 961.02, Germicidal Spray Products as Disinfectants (2012) (*copy provided*)			
Application Method		Ready-to-use, trigger spray			
Test Substance Preparation	**Name/ID**	Everclean; e0111-136A			
	Lots **☐ 1 ☐ 2 ☒ 3**	Final Test Substance Certificates of Analysis: 2182-165: 2.34% Citric acid 2182-145: 2.38% Citric acid 2182-146: 2.37% Citric acid Tested concentration: LCL			
	Preparation	Ready-to-use spray at a distance of 6-8 inches using 3 sprays			
Soil load		5% FBS			
Carrier type, # per lot		Glass 1" x 1" carriers, 5 carriers			
Test conditions		**Contact time**	30 sec.	**Temp**	20°C
Neutralizer		1 carrier in 20 mL (Letheen Broth + 0.07% Lecithin + 0.5% Tween 80)		**Incubation**	45 hrs. at 36°C & 29°C
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)					

5.	**MRID**	50598918		
Exp. Start Date		3/21/18	**Study Completion Date:**	7/3/18
Study Objective		Hard, non-porous surface disinfectant – virus		
Study Title		Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces		
Testing Lab, Lab Study ID		Accuratus Lab Services, #A25059		
Test Method		Accuratus Lab Services Protocol #REK01121417.R39 ASTM E1053-11 *(copy provided)*		
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		Rhinovirus type 39, ATCC VR-340, Strain 209		
Indicator Cell Culture		WI-38 (human lung), ATCC CCL-75		
Test Medium		Minimum Essential Medium (MEM) + 10% (v/v) heat-inactivated FBS, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B.		
Application Method		Ready-to-use trigger spray		
Test Substance Preparation	**Name/ID**	Everclean; e0111-136A		
	Lots **☐ 1 ☒ 2 ☐ 3**	Final Test Substance Certificates of Analysis: 2182-145: 2.38% Citric acid 2182-146: 2.37% Citric acid Tested concentration: LCL		

	Preparation	Ready-to-use spray using 3 sprays at 6-8 inches			
Soil load		5% FBS			
Carrier type, # per lot		Glass carriers			
Test conditions		**Contact time**	10 min.	**Temp**	22°C
Neutralizer		Sephadex Gel Filtration Columns			
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)					

6.	**MRID**	50598919		
Exp. Start Date		3/27/18	**Study Completion Date:**	6/27/18
Study Objective		Hard, non-porous surface disinfectant – virus		
Study Title		Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces		
Testing Lab, Lab Study ID		Accuratus Lab Services, #A25058		
Test Method		Accuratus Lab Services Protocol #REK01121417.ROT ASTM E1053-11 *(copy provided)*		
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		Rotavirus, ATCC VR-2018, Strain WA		
Indicator Cell Culture		MA-104 (Rhesus monkey kidney), ATCC CRL-2378.1		
Test Medium		Minimum Essential Medium (MEM) + 10 µg/mL gentamicin, 100 units/mL penicillin, 2.5 µg/mL amphotericin B, 0.5 µg/mL trypsin, and 2.0 mM L-glutamine		
Application Method		Ready-to-use trigger spray		
Test Substance Preparation	**Name/ID**	Everclean; e0111-136A		
	Lots **☐ 1 ☒ 2 ☐ 3**	Final Test Substance Certificates of Analysis: 2182-145: 2.38% Citric acid 2182-146: 2.37% Citric acid Tested concentration: LCL		
	Preparation	Ready-to-use spray using 3 sprays at 6-8 inches		
Soil load		5% FBS		
Carrier type, # per lot		Glass carriers		
Test conditions		**Contact time**	10 min.	**Temp** 20°C
Neutralizer		Sephadex Gel Filtration Columns		
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)				

7.	**MRID**	50598920		
Exp. Start Date		3/29/18	**Study Completion Date:**	7/3/18
Study Objective		Hard, non-porous surface disinfectant – virus		
Study Title		Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces		

Testing Lab, Lab Study ID		Accuratus Lab Services, #A25057			
Test Method		Accuratus Lab Services Protocol #REK01121417.RSV ASTM E1053-11 *(copy provided)*			
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		Respiratory syncytial virus (RSV), ATCC VR-26, Strain Long			
Indicator Cell Culture		Hep-2 (human larynx carcinoma), ATCC CCL-23			
Test Medium		Minimum Essential Medium (MEM) + 2% (v/v) heat-inactivated FBS, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B			
Application Method		Ready-to-use trigger spray			
Test Substance Preparation	**Name/ID**	Everclean; e0111-136A			
	Lots ☐ 1 ☒ 2 ☐ 3	Final Test Substance Certificates of Analysis: 2182-145: 2.38% Citric acid 2182-146: 2.37% Citric acid Tested concentration: LCL			
	Preparation	Ready-to-use spray using 3 sprays at 6-8 inches			
Soil load		5% FBS			
Carrier type, # per lot		Glass carriers			
Test conditions		**Contact time**	10 min.	**Temp**	20°C
Neutralizer		Sephadex Gel Filtration Columns			
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		**Test History:** The initial assay performed on March 29, 2018 was repeated on April 27, 2018 due to test substance cytotoxicity preventing demonstration of a 3-log reduction in titer beyond the cytotoxic level. Therefore, the data from the March 29, 2018 assay is considered invalid and is presented in Attachment I. Valid results were obtained from the assay performed on April 27, 2018 and are presented in the body of the report.			

V. RESULTS

Bactericidal Activity						
MRID No.	**Contact Time**	**Organism**	**No. Carriers Exhibiting Growth/ Total Carriers**			**Average Carrier Population Control Log (CFU/Carrier)**
			B: 2182-165	**B: 2182-145**	**B: 2182-146**	
50598914	5 min.	*Pseudomonas aeruginosa* (ATCC 15442)	**3/12/18** 0/60	**3/5/18** 0/60	**3/5/18** 0/60	3/5/18: 5.35 3/12/18: 5.54
50598915	**3/5/18** 5 min.	*Staphylococcus aureus* (ATCC 6538)	2/60	2/60	1/60	5.19
	3/21/18 10 min.		0/60	1/60	--	5.63
50598916	5 min.	*Salmonella enterica* (ATCC 10708)	0/60	0/60	0/60	4.49

Hard, Non-Porous, Non-Food Contact Surface Sanitizer						
Contact Time	**MRID No.**	**Organism**	**Results**			**Carrier Population Average Log_{10} CFU/carrier**
			Batch No.	**Average CFU/carrier**	**Percent Reduction**	
30 sec.	50598917	*Staphylococcus aureus* (ATCC 6538)	**2182-145**	$<2.00 \times 10^1$ (<1.30)	99.999	2.00×10^6 (6.30)
			2182-146	$<2.00 \times 10^1$ (<1.30)	99.999	
			2182-165	$<2.00 \times 10^1$ (<1.30)	99.999	
		Enterobacter aerogenes (ATCC 13048)	**2182-145**	$<2.00 \times 10^1$ (<1.30)	>99.99926	2.69×10^6 (6.43)
			2182-146	$<2.00 \times 10^1$ (<1.30)	>99.99926	
			2182-165	$<2.00 \times 10^1$ (<1.30)	>99.99926	

Virucidal Activity						
MRID No.	**Contact Time**	**Organism**	**Results**			**Plate Recovery Control ($TCID_{50}$/100µL)**
				Batch# 2182-145	**Batch# 2182-146**	
50598918	10 min.	Rhinovirus type 39, ATCC VR-340, Strain 209	**Description**	**Rep. 1**	**Rep. 1**	$10^{4.50}$
			Complete Inactivation	10^{-2} to 10^{-6} dilutions	10^{-2} to 10^{-6} dilutions	
			$TCID_{50}$/100µL	$\leq 10^{1.50}$	$\leq 10^{1.50}$	
			Log_{10} Reduction	≥3.00	≥3.00	
50598919		Rotavirus, ATCC VR-2018, Strain WA	**Description**	**Rep. 1**	**Rep. 1**	$10^{5.50}$
			Complete Inactivation	10^{-2} to 10^{-8} dilutions	10^{-2} to 10^{-8} dilutions	
			$TCID_{50}$/100µL	$\leq 10^{1.50}$	$\leq 10^{1.50}$	
			Log_{10} Reduction	≥4.00	≥4.00	
50598920		Respiratory syncytial virus (RSV), ATCC VR-26, Strain Long	**Description**	**Rep. 1**	**Rep. 1**	$10^{5.50}$
			Complete Inactivation	10^{-2} to 10^{-6} dilutions	10^{-2} to 10^{-6} dilutions	
			$TCID_{50}$/100µL	$\leq 10^{1.50}$	$\leq 10^{1.50}$	
			Log_{10} Reduction	≥4.00	≥4.00	

VI. CONCLUSION

MRID #	Claim	Surface Type	Application Method(s) and Dilution	Contact Time	Soil load	Diluent	Organism(s)	Data support tested conditions?
50598914	Bactericidal activity	Hard, non-porous surfaces	RTU Spray	5 min.	5%	None	*Pseudomonas aeruginosa* (ATCC 15442)	**Yes**

50598915	Bactericidal activity	Hard, non-porous surfaces	RTU Spray	10 min.	5%	None	*Staphylococcus aureus* (ATCC 6538)	**Yes**
50598916	Bactericidal activity	Hard, non-porous surfaces	RTU Spray	5 min.	5%	None	*Salmonella enterica* (ATCC 10708)	**Yes**
50598918	Virucidal activity	Hard, non-porous surfaces	RTU Spray	10 min.	5%	None	Rhinovirus type 39, ATCC VR-340, Strain 209	**Yes**
50598919	Virucidal activity	Hard, non-porous surfaces	RTU Spray	10 min.	5%	None	Rotavirus, ATCC VR-2018, Strain WA	**Yes**
50598920	Virucidal activity	Hard, non-porous surfaces	RTU Spray	10 min.	5%	None	Respiratory syncytial virus (RSV), ATCC VR-26, Strain Long	**Yes**
50598917	Non-food contact surface sanitizer	Hard, non-porous surfaces	RTU Spray	30 sec.	5%	None	*Enterobacter aerogenes* (ATCC 13048), *Staphylococcus aureus* (ATCC 6538)	**Yes**

MRID (year)	**Emerging virus claim**	**Organism(s)**	**Type of Virus**	**Surface Type**	**Application Method(s) and/or Dilution**	**Contact Time**	**Soil load**	**Study(ies) support listed virus(es)**
50598918	Enveloped Virus & Large Non-Enveloped Virus	Rhinovirus type 39, ATCC VR-340, Strain 209	Small, non-enveloped virus	Hard non-porous surface	RTU Spray	10 min.	5% FBS	Yes

VII. LABEL RECOMMENDATIONS (for label dated August 2, 2018)

1. The proposed label claims are acceptable regarding the use of the product, Everclean, EPA Reg. File No. 777-RGL, as a ready-to-use spray disinfectant with bactericidal activity against the following organisms for use on hard, non-porous surfaces at the indicated contact time when sprayed at the distance of 6-8 inches from the surface:

Organism	Contact time
Pseudomonas aeruginosa (15442)	5 min.
Salmonella enterica (ATCC 10708)	5 min.
Staphylococcus aureus (ATCC 6538)	10 min.

These claims **are supported** by the applicant's data.

2. The proposed label claims are acceptable regarding the use of the product, Everclean, EPA Reg. File No. 777-RGL, as a ready-to-use spray disinfectant with virucidal activity against the following organisms for use on hard, non-porous surfaces at 10 minutes when sprayed at the distance of 6-8 inches from the surface.

   Rhinovirus type 39, ATCC VR-340, Strain 209
   Rotavirus, ATCC VR-2018, Strain WA
   Respiratory syncytial virus (RSV), ATCC VR-26, Strain Long

   These claims **are supported** by the applicant's data.

3. The proposed label claims are acceptable regarding the use of the product, Everclean, EPA Reg. File No. 777-RGL, as a ready-to-use spray sanitizer against the following organisms for use on hard, non-porous, non-food contact surfaces at 30 seconds when sprayed at the distance of 6-8 inches from the surface:

   Klebsiella pneumoniae (ATCC 4352)
   Staphylococcus aureus (ATCC 6538)

   These claims **are supported** by the applicant's data.

4. The proposed label claims that the product, Everclean, EPA Reg. File No. 777-RGL, qualifies for the following emerging viral pathogens claims are acceptable.

For an emerging viral pathogen that is a/an…	*…following the directions for use for the following organisms on the label:*
Enveloped virus	Rhinovirus type 39, ATCC VR-340, Strain 209
Large, non-enveloped virus	Rhinovirus type 39, ATCC VR-340, Strain 209

   These claims are **acceptable** as they are supported by the cited data, however the proposed label language should exactly match the following:

   "This product qualifies for emerging viral pathogen claims per the EPA's 'Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels' when used in accordance with the appropriate use directions indicated below.

   This product meets the criteria to make claims against certain emerging viral pathogens from the following viral category[ies]:
   - Enveloped Viruses
   - Large, non-enveloped virus

For an emerging viral pathogen that is a/an…	*…follow the directions for use for the following organisms on the label:*
Enveloped virus	Rhinovirus type 39, ATCC VR-340, Strain 209

Large, non-enveloped virus	Rhinovirus type 39, ATCC VR-340, Strain 209

Acceptable claim language:

[Product name] *has demonstrated effectiveness against viruses similar to* ***[name of emerging virus]*** *on hard,* ***[porous and/or non-porous surfaces]****. Therefore,* ***[product name]*** *can be used against* ***[name of emerging virus]*** *when used in accordance with the directions for use against* ***[name of supporting virus(es)]*** *on* ***[hard, porous/non-porous surfaces]****. Refer to the* ***[CDC or OIE]*** *website at* ***[pathogen-specific website address]*** *for additional information.*

[Name of illness/outbreak] *is caused by* ***[name of emerging virus]. [Product name]*** *kills similar viruses and therefore can be used against* ***[name of emerging virus]*** *when used in accordance with the directions for use against* ***[name of supporting virus(es)]*** *on* ***[hard, porous/non-porous surfaces]****. Refer to the* ***[CDC or OIE]*** *website at* ***[website address]*** *for additional information.*"

5. Throughout the label, remove all claims that imply elimination of bacteria and/or viruses as efficacy data do not demonstrate complete kill. For example, remove "eliminates" from:
   - (Kills) (Eliminates) (Disinfects) (bacteria) {insert organisms – see Appendix 1} while it cleans tough (bathroom) (restroom) messes.
   - (Kills) (Eliminates) (Disinfects) common (household) bacteria and (viruses) without bleaching
   - (Kills) (Eliminates) (Disinfects) common (household) germs without bleaching

   The claim to eliminate 99.9% of bacteria is acceptable. However, please remove brackets from "99.9% of" when used with the word "eliminate".

6. The symbol designation qualifier for germ "**" should be revised to list or refer to the qualifying organisms (e.g. *Pseudomonas aeruginosa*, *Salmonella enterica*, *Staphylococcus aureus* and Rhinovirus). The symbol should be unique and should not be used as a qualifier for other references.

7. Throughout the label, please qualify all germ claims, including "germ killing" and "germ killers" as described above in comment 6.

8. On page 2 of the proposed label,
   a. Remove "Meets AOAC Standards" from "Graphic Symbol (Hospital Disinfectant – Meets AOAC Standards)".
   b. Revise the claim "(This product) meets AOAC Germicidal Spray efficacy standards for hospital disinfectants" to "(This product) is tested according to AOAC Germicidal Spray testing method". AOAC does not have efficacy standards for hospital disinfectants.
   c. Remove "Quick" from the claim "Quick & Easy". Claims for quick are limited to contact times of 30 seconds or less and this claim references disinfection with a contact time of 10 minutes.

9. On page 3 of the proposed label,
   a. Remove the claims "Power Foam", "Fast acting foam", and "Powerful foaming

action". These claims are ambiguous and could be referring to disinfection or sanitization. Alternatively, these claims may be qualified to reference non-pesticidal uses.

b. Remove "eliminators" from the claim "(Credible) (effective) (Efficient) (Fantastic) (Incredible) (Proven) (Unbeatable) Germ (killers) (slayers) (destroyers)(eliminators) (removers) (neutralizers) (terminators) ({insert active ingredient – see CSF})" and "(Dependable) (Trusted) (Reliable) Germ (killers) (slayers) (destroyers) (eliminators) (removers) (neutralizers) (terminators) ({insert active ingredient – see CSF}). Efficacy data did not demonstrate elimination of germs." Efficacy data did not demonstrate elimination.

c. Remove "(Disinfecting) (Sanitizing) (Germ Killing) Heroes ({insert active ingredient – see CSF})" as it may be misleading to the user. It is unclear what a Disinfecting/Sanitizing/Germ Killing Heroes mean.

10. On page 4,
    a. Remove "High power foam", "Power (plus) + (Active Shield Technology)", "Powerful foam (destroys) (removes)…", and "Powerful foaming action (for) (dissolves) (tough)…". Refer to rationale from recommendation #9.a. Alternatively, the claims may specify for cleaning and/or stain removing actions only. Removing brackets from {insert soils – see Appendix 2} is another alternative.
    b. Remove the claim "Just spray & walk away". The contact time should be monitored after spraying the product, and users should not walk away until the contact time is achieved.
    c. Remove brackets from ({insert soils – see Appendix 2}) from the following:
        - Prevents build-up of (dirt) ({insert soils – see Appendix 2}) where bacteria can thrive
        - Prevents ({insert soils – see Appendix 2}) from coming back

11. On page 5,
    a. Remove brackets from ({insert soils – see Appendix 2}) from the following:
        - Tough on ({insert soils – see Appendix 2})
        - (Tough) (the toughest) (stubborn) ({insert soils – see Appendix 2}) disappear in seconds
    b. The claim "One step cleaning and sanitizing" should specify "when use-directions for sanitization are followed".
    c. Under "DISINFECTING CLAIMS", remove "30 seconds" from the claim "Effective against: {insert organisms – See Appendix 1} in (30 seconds) (10 minutes)". This claim is misleading because 30 second contact time does not apply to disinfection.

12. On page 6, under the section titled "DISINFECTING CLAIMS - Hard, non-porous surface",
    a. Remove "in seconds" from the claim "(Kills (Eliminates) (Disinfects) 99.9% of bacteria and viruses on hard, non-porous surfaces in seconds". This claim is misleading because "in seconds" does not apply to disinfection.
    b. Remove "30 seconds" from the claim "(Kills) (Eliminates) (Disinfects) (99.9% of) ({insert organisms – see Appendix 1}) in (30 seconds) (10 minutes)". This claim is misleading.
    c. Remove "and sanitizes without bleaching" from the claim "Kills (household)

bacteria (and sanitizes without bleaching)". This is misleading because the claim falls under the section titled "<< DISINFECTING CLAIMS – Hard, non-porous surface >>"

d. Remove "more than" from the claim "Kills more than 99.9% of bacteria and viruses"
e. Revise the claim "Prevents the spread of harmful (household) germs** between treated hard, non-porous surfaces" to "Reduces the spread of harmful (household) germs between treated hard, non-porous surfaces".
f. Remove "Starts (killing) (to kill) 99.9% of germs on contact". This is misleading because a contact of 5 minutes (for *P. aeruginosa* and *S. enterica*) or 10 minutes (for *S. aureus* and the tested viruses) is required for disinfection.

13. Under the Use Directions, the direction "To Disinfect/Sanitize (hard non-porous surfaces)" should be revised to specify "spraying of product from the distance of 6-8 inches from the surface" to reflect the efficacy testing method.